

### REMARKS

Claims 1-5, 7, 8, 17, 18, and 28-37 were pending in the present application and claims 17 and 18 have been withdrawn from consideration. Claims 17 and 18 have been amended to particularly point out and distinctly claim certain encompassed subject matter. Support for the present amendment may be found in the application as originally filed, for example, in the published specification at paragraphs 0021, 0092, 0106 and 0108; in original claims 1, 2 and 9; and elsewhere. No new matter has been added by the present amendment.

#### DOUBLE PATENTING REJECTIONS

A. The PTO rejects claims 1-5, 7-8 and 28-37 under the judicially created doctrine of obviousness-type double patenting over claims 1-17 of U.S. Patent No. 7,655,787 for the reasons asserted in the Office Action.

Applicants respectfully traverse these grounds for rejection and submit that the instant claims are directed to subject matter that is patently distinguishable from the subject matter encompassed by claims 1-17 of U.S. Patent No. 7,655,787, *inter alia*, where, contrary to the PTO's assertion, claims 1-17 of U.S. 7,655,787 do not recite a "polyvalent complex". Instead, claims 1-17 of the '787 patent are directed to a pRNA chimera. Hence, the subject matter of the present claims would not be an obvious variation of the cited claims, claims 1-17 of the '787 patent, even in view of Chen et al. (*J Biol Chem* 2000 275:17510) as also cited by the PTO. In particular, Chen et al. merely describe native pRNA, but Chen et al. are completely silent with respect to a pRNA chimera, such that no teaching or suggestion can be found therein upon which a skilled person would reasonably have expected successfully to assemble the present polyvalent multimeric complex from a plurality of chimeric pRNA monomers, when the pRNA taught by Chen et al. is *not* chimeric pRNA.

Nevertheless, without acquiescence in any rejection and solely for purposes of advancing the prosecution of the present application, applicants submit herewith a Terminal Disclaimer (TD) with respect to U.S. Patent No. 7,655,787. Accordingly, applicants respectfully request withdrawal of this obviousness-type double patenting rejection.

B. The PTO also provisionally rejects claims 1-5, 7-8 and 28-37 under the judicially created doctrine of obviousness-type double patenting over claims 15, 16 and 19-29 of copending U.S. Application No. 11/989,590, for the reasons asserted in the Office Action.

Applicants respectfully traverse these grounds for rejection and submit that as a *provisional* double patenting rejection, it may be maintained until it is the *only* remaining rejection in the present application (M.P.E.P. §804(I)(B)). Nevertheless, without acquiescence in any rejection and solely for purposes of advancing the prosecution of the present application, applicants submit herewith a Terminal Disclaimer (TD) with respect to copending application number 11/989,590. Accordingly, applicants respectfully request withdrawal of this provisional obviousness-type double patenting rejection.

#### REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-5, 28-32 and 35-37 stand rejected under 35 U.S.C. §102(a) for alleged lack of novelty over Hoeprich et al. (August 2003 *Gene Therapy* 10:1258). In particular, the Examiner asserts that Hoeprich et al. teach the recited combination of features, namely, a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers that each independently comprise a heterologous component (which may be siRNA or a ribozyme), wherein at least one pRNA chimera comprises an end-labeling agent.

Applicants respectfully traverse these grounds for rejection. The instant embodiments are directed in pertinent part to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, each said chimeric pRNA monomer independently comprising a heterologous component that comprises a biologically active RNA.

Applicants respectfully submit that the publication of Hoeprich et al. is not available as prior art in the present application. The PTO therefore fails to establish a *prima facie* case of anticipation under §102(a) because the presently claimed invention was not “known or used by others in this country, or patented or described in a printed publication . . . *before* the invention thereof by the applicant for a patent.” (§102(a), emphasis added). Specifically, and as applicants previously noted in the response that was submitted to the PTO on December 23, 2010, the present application claims priority as a continuation-in-part to, *inter alia*, U.S.A.N.

10/373,612 (February 24, 2003), which is a CIP of PCT/US01/26333 (August 23, 2001), which claims the benefit of U.S.A.N. 60/277,393 (August 23, 2000).)

Hoeprich et al. published in August 2003. Looking to U.S.A.N. 10/373,612, filed on February 24, 2003, from which the present application claims the benefit of priority, it is submitted that at least as early as February 24, 2003, the applicants had invented the subject matter encompassed by the instant claims. The publication of Hoeprich et al. therefore did not appear “before the invention” by the applicants of the presently claimed invention embodiments.

For example, at paragraphs 0091-0092 of the specification of priority document U.S.A.N. 10/373,612 (filed on February 24, 2003; published as US 2004/0126771; now issued as U.S. Patent No. 7,655,787), and in Figure 7 of U.S.A.N. 60/433,697 and in the final paragraph at page 26 therein, applicants disclose a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers that each independently comprise a heterologous component, which may be a biologically active RNA. At paragraphs 0007 and 0073, and in original claims 2, 5 and 13 of the same priority document, U.S.A.N. 10/373,612 (filed on February 24, 2003; published as US 2004/0126771; now issued as U.S. Patent No. 7,655,787), applicants disclose species of biologically active RNA that include siRNA, antisense RNA, an RNA aptamer and a peptide nucleic acid (PNA).

It is therefore respectfully submitted that Hoeprich et al. (August 2003) cannot be properly cited as a reference by the PTO. Reconsideration is therefore requested in view of the disclosure of the priority document U.S.A.N. 10/373,612 (filed February 24, 2003). Moreover, where independent claims 1 and 28 are free of the art in view of the unavailability of Hoeprich et al. to the PTO, it is submitted that the instant claims that depend therefrom (*e.g.*, claims 2-5, 29-32 and 35-37) must also necessarily be free of the art.

It is therefore submitted further that the instant claims (1-5, 28-32 and 35-37) fully satisfy the requirements of 35 U.S.C. §102. Reconsideration and withdrawal of the rejections are therefore respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103

The PTO rejects claims 1-8 and 28-37 under 35 U.S.C. §103 for alleged obviousness over Hoeprich (August 2003 *Gene Therapy* 10:1258) and Bennett et al. (U.S. Pat. No. 5,998,148). As noted above, the PTO asserts that Hoeprich et al. teach a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers that each independently comprise a heterologous component, wherein at least one pRNA chimera comprises an end-labeling agent. The PTO concedes, however, that Hoeprich et al. do not teach that at least one pRNA incorporates a nucleotide analog. Bennett et al. is alleged to remedy the deficiencies of Hoeprich et al. by teaching modified nucleotides such as 2'F modifications. The Examiner asserts that the person having ordinary skill in the art would reasonably have expected to modify the pRNA of Hoeprich et al. using the nucleotide analogues of Bennett et al.

Applicants respectfully traverse these grounds for rejection. The instant embodiments are directed in pertinent part to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, each said chimeric pRNA monomer independently comprising a heterologous component that comprises a biologically active RNA.

For reasons given above in response to the rejections under §102, it is submitted that the PTO may not properly cite Hoeprich et al. (August 2003) under §103, where this later-published reference is not available as prior art in view of applicants' priority claim to, *inter alia*, U.S.A.N. 10/373,612, which was filed on February 24, 2003. As such, Hoeprich et al. must be withdrawn as a reference. Bennett et al. are asserted by the PTO merely to teach nucleic acid molecules comprising modified nucleotides such as 2'F modifications. Applicants respectfully submit that the teachings of Bennett et al. taken alone merely pertain to chemically modified nucleotides but fail to teach or in any way suggest anything having to do with pRNA, much less with a chimeric pRNA, and Bennett et al. certainly fail to teach or suggest a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, each said chimeric pRNA monomer independently comprising a heterologous component that comprises a biologically active RNA.

Accordingly, where Hoeprich et al. are not available as prior art, for reasons given above, the PTO fails to establish a *prima facie* case of obviousness under 35 U.S.C. §103. Reconsideration and withdrawal of the present rejections are therefore respectfully requested.

REQUEST FOR REJOINDER

Applicants understand that if claims directed to a product are elected for examination and found to be allowable, then withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim may later be rejoined to the application, under 37 C.F.R. §1.142. Rejoinder of previously withdrawn claims 17 and 18 is therefore respectfully requested. Applicants note that these claims directly or indirectly recite the subject matter of claim 1, which for reasons given herein is now believed to be in allowable form.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,  
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Enclosures:  
Terminal Disclaimers (2)  
Supplemental Information Disclosure Statement  
Cited References (32)

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